

REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1-24 are pending in this application. No claims are amended, added or cancelled. Claim 1 is the sole independent claim.

Applicants note with appreciation the Examiner's acknowledgement of a claim for foreign priority under 35 U.S.C. §119. Action, Summary at 12. Applicants respectfully request that the Examiner's next communication include an acknowledgement of receipt of the certified copies of the priority documents from the International Bureau.

Applicants also respectfully note the present action indicates that the drawings have been accepted by the Examiner. Action, Summary at 10.

Example Embodiments of the Present Application

Independent claim 1 recites a method comprising forming homopolymers or copolymers of TMC; molding said polymers formed into a desired shape; and irradiating said molded shape with actinic radiation in an inert atmosphere. As is illustrated in on page 14, table 3 and page 15, table 4 of the present application, irradiating the polymers in an air atmosphere does not allow for desirable properties. For example, table 4 clearly shows that the plateau creep rate of air irradiated samples is undesirable compared to the non-irradiated samples. On page 7, lines 20-31, of the application, the creep rate is an important factor in determining the suitability of the present polymeric structures.

Rejections under 35 U.S.C. § 102(a)/103(a)

Pêgo et al.

Claims 1-2 and 8-24 stand rejected under 35 U.S.C. § 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Anna Paula Pêgo et al. (*Polymer*, volume 44, issue 21, October 2003, pages 6495-6504) ("Pêgo"). Applicants respectfully traverse this rejection for the reasons detailed below.

Applicants submit that Pêgo is not a prior art reference under any section of 35 U.S.C. §102. With respect to §102(a), §102(b) and §102(e), the present application's effective U.S. filing date (November 5, 2002) predates Pêgo's earliest publication date (October 2003).

The Pêgo reference was published in October 2003. Accordingly, Pêgo's date for the purpose of a §102 rejection is October 2003.

Applicants note that the present application claims priority under 35 U.S.C. § 119 to the Netherlands Application No. 10-21843, filed on November 5, 2002 and PCT Application No. PCT/EP2003/012425, filed on November 5, 2003. Applicants may be able to overcome a 35 U.S.C. §102 rejection by proving he or she is entitled to his or her own 35 U.S.C. §119 priority date which is earlier than the reference's publication date. *See* MPEP § 2136.03.

Applicants make a proper claim for priority under 35 U.S.C. §119. The specification of the present application contains a specific reference to Netherlands Application No. 10-21843. A certified priority document of Netherlands Application No. 10-21843 and a verified English translation of the priority document to perfect the claim to priority to Netherlands Application No. 10-21843 is enclosed herewith. Accordingly, the present application's effective filing date for the purpose of overcoming any §102 rejection is November 5, 2002.

Therefore, the Applicants contend that Pêgo is not “prior art” with respect to the pending application and cannot, therefore, serve as the basis for any valid rejection under 35 U.S.C. § 102.

The Applicants, therefore, respectfully request that the rejection to Claims 1-2 and 8-24 under 35 U.S.C. § 102(a) or 103(a) be withdrawn.

Rejections under 35 U.S.C. § 102(b)/103(a)

Ritter et al.

Claims 1, 3-4, 8-9, 12-18, 21 and 23-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Ritter et al. (U.S. Patent No. 4,496,446). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action states that Ritter et al. teaches irradiating structural surgical elements, such as an anastomosis ring device, with gamma radiation to improve properties such as initial strength, *in vivo* strength and degradation loss rate of said strength properties; that said surgical elements are made of bioabsorbable polymers, such as polyglycolides and copolymers of glycolides with trimethylene carbonate; that Ritter et al. discloses the use of gamma radiation dosages of up to 10 Mrad (100 kGy); that, in addition, Ritter et al. teaches ethylene oxide sterilization of said structure surgical devices; that, regarding the properties as found in claims 12-14, Ritter et al. discloses a method that anticipates the claimed invention as written therefore it is deemed the properties should be inherent to the irradiated devices of Ritter et al.; that, in the alternative, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants’ composition differs and, if so, to what extent, from the discussed reference; and that, therefore, with the showing of the reference, the burden of

establishing non-obvious by objective evidence is shifted to the Applicants. Applicants respectfully disagree.

Ritter relates to glycolide polymers, which are described as unsuitable prior art co-polymers on page 1, line 32 to page 2, line 3 of the present application due to their glass transition temperature. Therefore, Applicants respectfully submit that glycolide polymers do not correspond with the TMC co-polymers of independent claim 1, nor would one of ordinary skill in the art be led to use the glycolide polymers of Ritter in the method of claim 1.

Further, in example 7 of Ritter, the hypothetical copolymer may be irradiated (sterilized) in an air atmosphere (column 8, lines 4-11), rather than an inert atmosphere as recited in claim 1.

Claims 3-4, 8-9, 12-18, 21 and 23-24, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1, 3-4, 8-9, 12-18, 21 and 23-24 under 35 U.S.C. § 102(b) or 103(a) be withdrawn.

Rejections under 35 U.S.C. § 102(e)/103(a)

Huang et al.

Claims 1-4, 8-9, 11, 15-21 and 23-24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Huang et al. (U.S. Patent No. 7,037,983 and U.S. Publication No. 2003/0232929). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that Huang et al. teaches methods of making functional biodegradable polymers; that said modifications are obtained by polymerizing a vinyl monomer with a biodegradable polymer in the presence of an initiator system, such as a photoinitiator with

a light source, that said biodegradable polymers include synthetic polymers such as copolymers of TMC, i.e., poly (glycolic acid-co-trimethylene carbonate) copolymer; that said irradiation sources include UV and other high ionizing radiation and other energy irradiation sources; that, therefore it is deemed that the irradiation sources found in claim 8 are envisioned within the reference; that the biodegradable polymers of Huang et al. are disclosed as useful for biodegradable materials for usage in biomedical applications; that and that Huang et al. does not expressly teach the number average molecular weight of the polymers with TMC, however since applicant has not established the criticality of the molecular weights as instantly claimed it is deemed that any molecular weight homopolymers/copolymers would have worked equally as well in the absence of evidence to the contrary and/or unexpected results. Applicants respectfully disagree.

Huang et al, discloses a method for functionalizing biodegradable polymers by a direct reaction of the biodegradable polymers in the medium of functional monomers, particularly vinyl polymers (column 3, lines 60-64). Although the disclosure is among a long list of known biodegradable polymers which can be further functionalized with vinyl polymers (column 5, line 58), Applicants submit that Huang does not teach or suggest "forming homopolymers or copolymers of TMC" as recited in claim 1, and further does not teach molding of these polymers and subsequent irradiation of the structure in an inert atmosphere as recited in claim 1. The irradiation discussed by the Examiner is used to couple the vinyl monomers to the biodegradable polymer in a solution (thus, not in an inert atmosphere).

Claims 2-4, 8-9, 11, 15-21 and 23-24, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1-4, 8-9, 11, 15-21 and 23-24 under 35 U.S.C. § 102(e) or 103(a) be withdrawn.

Rejections under 35 U.S.C. § 102(b)/103(a)

Roby et al.

Claims 1, 3-4, 8-9, 12-18, 21 and 23-24 stand rejected under 35 U.S.C. § 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Roby et al. (U.S. Patent No. 5,889,075). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner stated that Roby et al. sets forth irradiated surgical sutures and methods of making them; that said surgical sutures are fabricated from a copolymer of dioxanone, trimethylene carbonate, and glycolide, which is treated with gamma irradiation to enhance the properties; that said copolymers can be arranged in sequences; that the irradiation treatment is from a total dose rate from about 2 to about 12 Mrad in an inert atmosphere while under vacuum; that, thus, the Examiner deems claims 10 and 11 are envisioned in the reference; that, regarding the properties as found in claims 12-14, Roby et al. discloses a method that anticipates the claimed invention as written therefore it is deemed the properties should be inherent to the irradiated devices of Ritter et al.; that, in the alternative, since the Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether Applicants' composition differs and, if so, to what extent, from the discussed reference; and that, therefore, with the showing of the reference, the burden of establishing non-obvious by objective evidence is shifted to the Applicants. Applicants respectfully disagree.

Roby relates to glycolide polymers, which are described as unsuitable prior art polymers on page 1, line 32 to page 2, line 3 of the present application due to their glass transition temperature. Therefore, Applicants respectfully submit that glycolide polymers do not correspond with the TMC co-polymers of independent claim 1, nor would one of ordinary skill in the art be led to use the glycolide polymers of Roby in the method of claim 1.

Further, column 1, lines 45-46 of Roby et al. discloses use of a terpolymer, and not a co-polymer, to identify the polymers concerned (see also claim 1). The disclosed structures in Roby are made of a combination of a co-polymer of glycolide as the predominant component co-polymerized with TMC (block A, column 2, lines 14-31) and copolymers of 1,4-dioxane-2-one (block B, column 2, lines 31-36). Therefore, Applicants submit that Roby does not teach or suggest "forming homopolymers or copolymers of TMC" as recited in claim 1

Claims 3-4, 8-9, 12-18, 21 and 23-24, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1, 3-4, 8-9, 12-18, 21 and 23-24 under 35 U.S.C. § 102(b) or 103(a) be withdrawn.

Rejections under 35 U.S.C. § 102(e)

Amsden et al.

Claims 1, 3-9, 18, 21 and 23-24 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Amsden et al. (U.S. Patent No. 6,984,393 and U.S. Publication No. 2003/0105245). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that Amsden et al. discloses photo- and thermally crosslinked biodegradable/biocompatible elastomeric polymers; that said crosslinked polymers can be useful in biomedical devices, such as scaffolds, that said polymers are elastomeric star polymers that have been combined with monomers and photoinitiators that are irradiated to produce said crosslinked polymers; that said radiation can be ultraviolet radiation; that said star polymer can be a carbonate such as trimethylene carbonate; that said crosslinked polymers are disclosed as being made into scaffolds for implantation, wherein Amsden et al. teaches sterilizing them prior to implantation; that this appears to anticipate the instantly claimed invention as written,

therefore, it is deemed the properties found in instant claims 12-14 are inherent to the Amsden et al. polymers; that, regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in a product-by-process claim; that the Patent Office can require Applicants to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on “inherency” under 35 U.S.C. § 102, on “*prima facie* obviousness” under 35 U.S.C. § 103, jointly or alternatively, burden of proof is same; that the Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require Applicants to prove that subject matter shown to be in prior art does not possess characteristics relied upon. Applicants respectfully disagree.

Amsden discloses a method for UV crosslinking of monomers thereby forming polymers, which are terpolymers of caprolactone/lactide copolymers rather than co-polymers of TMC as recited in claim 1. (see page 1, line 32 to page 2, line 3 of the present application). Further, the irradiation in Amsden is used to form polymers, rather than irradiating already formed and molded polymers as in claim 1.

Claims 3-9, 18, 21 and 23-24, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Applicants, therefore, respectfully request that the rejection to Claims 1, 3-9, 18, 21 and 23-24 under 35 U.S.C. § 102(e) be withdrawn.

Rejections under 35 U.S.C. § 102(b and/or e)

Pathak

Claims 1, 3-8, 12-14, 16-18 and 23-24 stand rejected under 35 U.S.C. § 102(b and/or e) as being anticipated by Pathak (U.S. Patent Nos. 7,211,651, 7,057,019 and 6,887,974 and U.S. Publication Nos. 2002/0114775 and 2003/0077272). Applicants respectfully traverse this rejection for the reasons detailed below.

The Examiner stated that Pathak sets forth polymeric crosslinking agents having an inert water-soluble component, a biodegradable component, and a functional component having reactive functional groups reactive with functional groups on proteins or other biological agents; that said polymeric crosslinking agents can be used to prepare hydrogels in applications, such as wound dressings; that said crosslinking takes place via irradiation with an ionizing radiation source; that, per figure 5, Pathak sets forth the use of TMC as an example of the biodegradable component; that Pathak sets forth photo-irradiating polymeric crosslinking agents should inherently have the properties as claimed in claims 12-14; that, regarding the products of claims 16, 18 and 23-24, the courts have held where the prior art discloses product that appears to be either identical with or only slightly different from product claimed in a product-by-process claim; that the Patent Office can require Applicants to prove that prior art products do not necessarily or inherently possess characteristics of his claimed product; whether rejection is based on “inherency” under 35 U.S.C. § 102, on “*prima facie* obviousness” under 35 U.S.C. § 103, jointly or alternatively, burden of proof is same; that the Patent Office that has reason to believe that functional limitation asserted to be critical for establishing novelty in claimed subject matter may, in fact, be inherent characteristic of prior art, possesses authority to require Applicants to prove that subject matter shown to be in prior art does not possess characteristics relied upon. Applicants respectfully disagree.

In column 12, lines 7 to 13, Pathak et al. discloses TMC and TMC copolymers as the biodegradable extension component of the subject crosslinkers, thus as part of a crosslinker (see also claim 5, rather than providing copolymers of TMC and subsequently shaping and irradiating these copolymers. The hydrogels according to Pathak et al. are not formed of TMC, but of, for example, PEG (see column 6, lines 51-61). TMC in Pathak et al. is only used as a part of a crosslinker for crosslinking polymers to larger structures such as a hydrogel. Therefore, Pathak et al. does not teach or suggest “forming at least one of homopolymers and copolymers of 1,3-trimethylene carbonate (TMC) into a desired shape, and irradiating said desired shape with actinic radiation in an inert atmosphere for crosslinking” as recited in claim 1.

Claims 3-8, 12-14, 16-18 and 23-24, dependent on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

The Applicants, therefore, respectfully request that the rejection to Claims 1, 3-8, 12-14, 16-18 and 23-24 under 35 U.S.C. § 102(b and/or e) be withdrawn.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicants hereby petition for a three (3) month extension of time for filing a reply to the outstanding Office Action and submit the required \$1050.00 extension fee herewith.

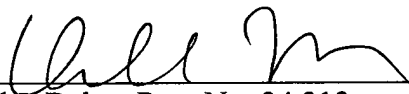
Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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